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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,972	04/07/2006	Takeshi Doi	288989US0PCT	5923
22850 7590 01/16/2008 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER O'DELL, DAVID K	
			ART UNIT 1625	PAPER NUMBER
			NOTIFICATION DATE 01/16/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/574,972	DOI ET AL.	
	Examiner	Art Unit	
	David K. O'Dell	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7 April 2006 & 29 June 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

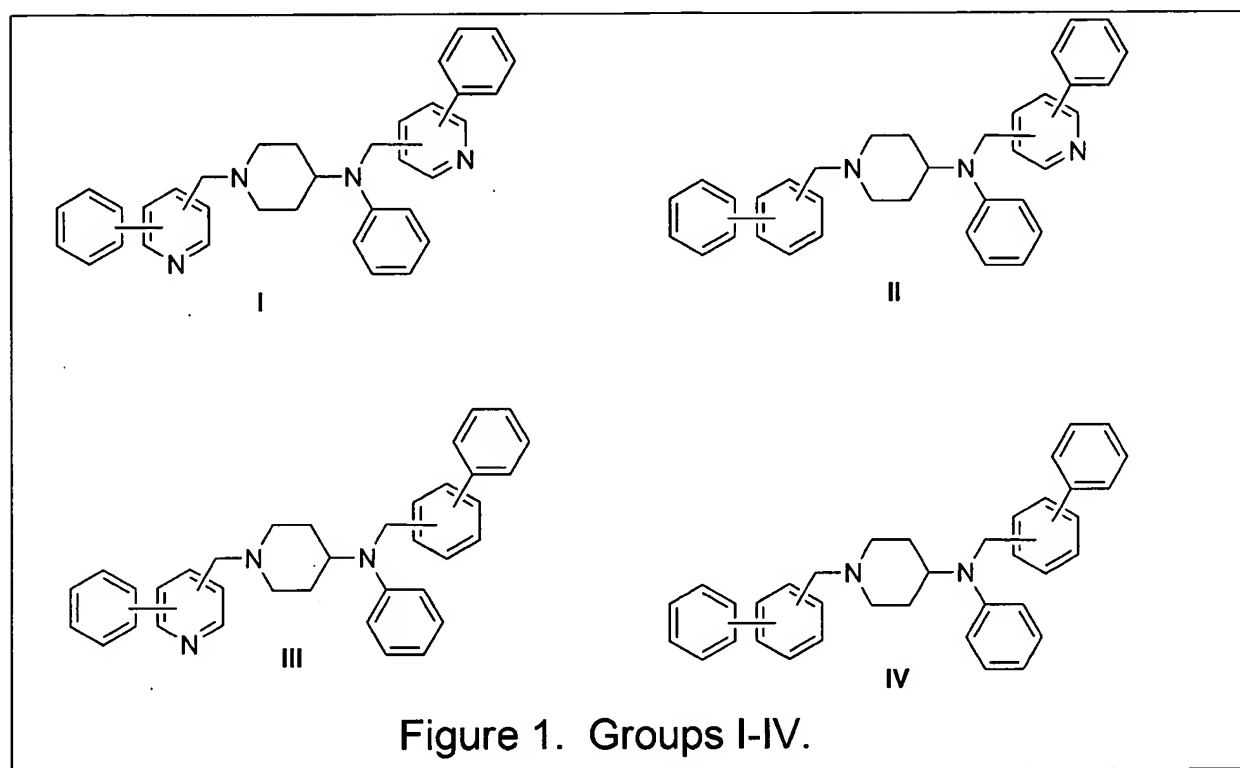
DETAILED ACTION

1. Claims 1-33 are pending.

Response to Restriction/Election

2. Applicant's election with traverse of Group V and the species "4-[N-(4-methoxyphenyl)-N-[[5-(3,4,5-trimethoxyphenyl)pyridin-3-yl]methyl]amino]-1-[[2-(3,4,5-trimethoxyphenyl)pyridin-4-yl] methyl] piperidine or a salt thereof, or a solvate thereof" in the reply filed on 16 December 2007 is acknowledged. A solvate or salt, is another species, and as such a "single species" is currently under examination. Should the compound be held allowable examination of salts and solvates of the elected species will be conducted. The traversal is on the ground(s) that it was improper because the examiner failed to show a lack of unity and that no search burden exists. Search burden is not a consideration under PCT Rule 13.1, but rather a special technical feature is the controlling factor. While the applicant has alleged that the examiner has failed to provide evidence that this special technical feature is not present, despite the fact that the examiner clearly showed the lack of novelty of the core, at applicant's behest, the examiner submits that U.S. Patent 6,395,753 shows that the compounds are in fact not novel, thus providing ample evidence that no special technical feature is present. It would appear that the applicant has failed to elect which group I-IV is being chosen for the method of treatment, however the examiner is assuming that based on the elected species the compounds of Group I are being chosen. The examiner rejoins group VI to group V. This application contains claims drawn to a nonelected invention with traverse. A complete reply to this action must include a cancellation of nonelected claims or other appropriate action.

Group V, claims 23-27, drawn to method of "inhibiting angiogenesis" with group I compounds pyridyl-piperidiny-pyridyl core where in formula 1 claim 1, l is 1; m is 0, X is NR₄, R₄ is phenyl, W1 = W2 = N, shown as structure I figure 1, classified in class 514 subclass various and, claims 28-33, drawn to methods of treating "a disease or pathological condition".



Priority

3. This application is a national stage of PCT/JP04/14956 filed 10/08/2004 which claims benefit of U.S. Provisional Application: 60/510,012 filed 10/10/2003. The U.S. provisional application is filed in a language other than English. An English translation of the non-English language provisional application and a statement that the translation is accurate must be filed in provisional application No. 60/510,012. See 37 CFR 1.78(a)(5). The English translation and a

statement that the translation is accurate required by 37 CFR 1.78(a)(5) is missing. Accordingly, applicant must supply 1) the missing English translation and a statement that the translation is accurate in provisional application No. 60/510,012 and 2) in the present application, a confirmation that the translation and statement were filed in the provisional application. If 1) and 2) are not filed (or the benefit claim withdrawn by the filing of an amendment or Supplemental Application Data Sheet) prior to the expiration of the time period set in this Office action, the present application will be abandoned. See 37 CFR 1.78(a)(5)(iv).

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 23-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U. S. patent 6,498,169 (cited on the IDS) in view of Bickwell et. al. *Tumour Angiogenesis* 1997, Oxford Univ. pg. 19. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- A) Determining the scope and contents of the prior art.
- B) Ascertaining the differences between the prior art and the claims at issue.
- C) Resolving the level of ordinary skill in the pertinent art.
- D) Considering objective evidence present in the application indicating obviousness or nonobviousness.

A) Determining the scope and contents of the prior art: The '169 patent teaches the elected species of the instant case, moreover the '169 patent also teaches that the elected species and other compounds of the instant case are inhibitors of endothelial cell adhesion (column 118 - 119, Table 1). Bickwell teaches that "alignment of endothelial cells into tube-like structures" or adhesion of these cells to one another, is a key step in angiogenesis. Moreover Bicknell teaches that angiogenesis is important for the growth of solid tumors.

B) Ascertaining the differences between the prior art and the claims at issue.

The process of the instant case involves the "inhibiting angiogenesis" and treating solid tumors with 4-[N-(4-methoxyphenyl)-N-[[5-(3,4,5-trimethoxyphenyl)pyridin-3-yl]methyl]amino]-1-[[2-(3,4,5-trimethoxyphenyl) pyridin-4-yl] methyl] piperidine, while the prior art teaches the inhibition of cell adhesion with 4-[N-(4-methoxyphenyl)-N-[[5-(3,4,5-trimethoxyphenyl)pyridin-3-yl]methyl]amino]-1-[[2-(3,4,5-trimethoxyphenyl) pyridin-4-yl] methyl] piperidine. It goes without saying that the compounds and their method of administration is identical. It would appear then that the applicant seems to believe that a new property has been discovered.

C) Resolving the level of ordinary skill in the pertinent art: The level of ordinary skill is high. Someone using these compounds would be a medical doctor.

D) Considering objective evidence present in the application indicating obviousness or nonobviousness: One of ordinary skill would have realized based on the teachings of Bicknell et. al. that inhibitors of endothelial cell adhesion would also find use as angiogenesis inhibitors and for the treatment of solid tumors. A person of ordinary skill in the art would have been motivated to do so based on the desire to treat tumors which are not desirable tissues

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 23-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-17 of U.S. Patent No. 6,395,753 in view of Bickwell et. al. *Tumour Angiogenesis* 1997, Oxford Univ. pg. 19. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims although drawn to "inhibiting angiogenesis" and methods of treating diseases caused by angiogenesis the '753 patent, covers methods of treating diseases caused by cell adhesion with the same compounds. See the 103(a) rejection above for a detailed discussion.

6. Claims 23-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-20 of U.S. Patent No. 6,498,169 in view of Bickwell et. al. *Tumour Angiogenesis* 1997, Oxford Univ. pg. 19. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current

claims although drawn to “inhibiting angiogenesis” and methods of treating diseases caused by angiogenesis the ‘169 patent, covers methods of treating diseases caused by cell adhesion with the same compounds. See the 103(a) rejection above for a detailed discussion.

7. Claims 23-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3 of U.S. Patent No. 6,605,620, in view of Bickwell et. al. *Tumour Angiogenesis* 1997, Oxford Univ. pg. 19. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims although drawn to “inhibiting angiogenesis” and methods of treating diseases caused by angiogenesis the ‘620 patent, covers methods of treating diseases caused by cell adhesion with the same compounds. See the 103(a) rejection above for a detailed discussion.

8. Claims 23-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-17 of U.S. Patent No. 6,867,221 in view of Bickwell et. al. *Tumour Angiogenesis* 1997, Oxford Univ. pg. 19. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims although drawn to “inhibiting angiogenesis” and methods of treating diseases caused by angiogenesis the ‘221 patent, covers methods of treating diseases caused by cell adhesion with the same compounds. See the 103(a) rejection above for a detailed discussion.

Specification

9. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested:

“4-[N-[[(3,4,5-trimethoxyphenyl)pyridinyl]methyl]amino] -1-[[(3,4,5 - trimethoxyphenyl)pyridinyl]methyl]piperidines angiogenesis inhibitors” or something similar.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David K. O'Dell whose telephone number is (571) 272-9071. The examiner can normally be reached on Mon-Fri 7:30 A.M.-5:00 P.M EST.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Primary examiner, Rita Desai can be reached on (571)272-0684. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D.K.O.

RITA DESAI
PRIMARY EXAMINER
RD Desai
1/8/08